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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,615	10/10/2001	Lisa A. Vala	5511USA	8746

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EXAMINER
SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	12

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,615	Applicant(s) VALA ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/18/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,10,15-17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 7, 10, 15-17, 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 19, 2003 has been entered.

Claims 1-3, 5, 7, 10, 15-17, 20 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 7, 10, 15-17, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations of the first component in the instant independent claims 1, 17, 20 are confusing. Claim 1 recites that the beneficial soluble is provided in amounts of 1 to 3 grams per serving and a protein content of at least 8%, wherein such component is selected from oat flour, oat bran and beta glucan. This language is confusing because it is not clear what is being selected from the group oat flour, oat bran or beta glucan. Is it the fiber component or the combination of fiber component and the protein? Further, if the later is the intended meaning, the language is still confusion because oat flour, oat

bran and beta glucan are carbohydrates and void of any protein content. Therefore, the scope of the claim 1 and the dependent claims thereof is ambiguous.

Claims 17 and 20 are also ambiguous because they recite a first beneficial health effect selected from the group oat flour, oat bran, and beta glucan. It is not clear how an effect can be selected from a particular product. There is no relationship between the claimed "health effect" and the claimed "oat flour, oat bran and beta glucan." Therefore claims are ambiguous in language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,3, 5, 15, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Sjoberg US Patent 6,491,952.

Sjoberg discloses cholesterol lowering baked cakes of 18-20 grams each containing 0.5 g of sitosterol or sitostanol and oat flakes (see example 9, claims 1-9). Sjoberg also teaches incorporation of casein and gelatin in the final compounds in amounts of at least about 28 grams in the final composition. Gelatin and Casein are proteins. Accordingly, Sjoberg anticipates the limitations of the instant claims.

Applicant's arguments that Sjoberg fails to teach the combination of stanol and the proteins have been considered but are not persuasive.

Sjoberg, in example 1, teaches the use of about 28 grams of gelatin in the final which amounts to about 30% of the final composition. Such amounts meet the instant limitation of "protein content of at least 8%." Therefore, Sjoberg anticipates the instant claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, 7, 10, 15-17, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sjoberg US Patent 6,491,952 in view of James US Patent 6,020,324.

The teachings of Sjoberg are discussed above. Sjoberg also teaches the use of his compositions in forming various food products such as a snack bar such as chocolate bars or other ready to eat food products such as yogurt. (col 2, lines 1-5). Sjoberg fails to explicitly teach products that lower LDL.

James is used to show that B-glucan containing food supplements are readily used to lower cholesterols including LDL (abstract, col 3, lines 12-35, col 6, lines 65-67; col 7, lines 1-50).

It is *prima facie* obvious to combine two compositions each of which is taught by prior at to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, claims that require no more than mixing together of two conventional spray-dried detergents set forth prima facie obvious subject matter. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the mixture of Sjoberg with those of James and then adjust the ratios of cholesterol lowering agents through routine experimentation to produce a food product of choice that provides LDL lowering effects, because as reasoned in *Kerkhoven* combining such ingredients flows logically from the teachings of Sjoberg and James.

Applicant's arguments with respect to this rejection have been fully considered, but are not found persuasive for the similar reasons set forth above. Essentially, Applicant appear to have misinterpreted the teachings of Sjoberg, because Sjoberg clearly contains gelatin and casein, which are proteins.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose

telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Shahnam Sharareh, PharmD
Patent Examiner, AU 1617

8/29/03